Medical Device Quality Management System in Turkey

Medical device quality management system in Turkey has been quickly changing over the years. Besides, the legal and political environment on medical device quality management systems are highly fragmented and thus complicated. Healthcare lawyers and relevant professionals face several challenges for finding out necessary procedures.

Introduction

Medical device quality management system in Turkey needs an innovative and comprehensive approach. It is far from simple to understand how the system operates in the healthcare sector. The present article will present targeted observations about the medical device quality management system in Turkey.

For our work and all legal services on the matter of healthcare, please click our Practice Areas, titled Healthcare.

What is meant by a medical device quality management system?

A medical device quality management system **(MDQMS)** refers to a set of processes guaranteeing that the involved medical device has a sufficient quality and safety for the intended use. Medical device quality management system covers a wide range of

activities including manufacturing, origin of country, risk management and supply chain management including distribution.

Does EU MDR apply to Turkey?

The EU-Turkey Customs Union Joint Committee declared the commitment of Turkey to provide full alignment of the Turkish legal framework on medical devices into line with EU rules including Medical Devices Regulation (EU) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746. Accordingly, EU standards and principles on medical devices are applicable to Turkey.

What are the labeling requirements for medical devices in Turkey?

There are critical obligations for medical devices in Turkey. First of all, all medical devices must have the CE marking in Turkey. What is more, medical devices should be registered in the online database system of the Ministry of Health. The Turkish Medicines and Medical Devices Agency, the main regulatory authority in Turkey, is granted to impose obligations and standards for medical devices.

Pi Legal Consultancy is a mecial device regulutary consultancy firm in Turkey.

How are medical devices regulated in Turkey?

The Medical Device Regulation has been fully implemented in the EU and in our country, simultaneously as of 26 May 2021. The In vitro Diagnostic Medical Device Regulation has been fully implemented as of 26 May 2022 in Turkey. Fundamental objective of those regulations is to create a transparent and sustainable medical device market in Turkey.

Which authorities are competent for medical device quality management in Turkey?

There are three main bodies in Turkey to regulate and supervise the medical device management market: the Ministry of Health, the Turkish Accreditation Agency and the Turkish Medicines and Medical Devices Agency.

Conclusion

In the light of the foregoing, this article concludes that understanding the medical quality management system in Turkey is beyond simple. Three executive institutions are granted different mandates and powers in the quality management. Medical professionals including healthcare lawyers carry out essential duties in the field of medical device environment. You can contact us for expert support on medical device regulutary consultant in Turkey.